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Consumer Choice and FDA Regulation of Sunlamp Products

Abstract

This paper explores the history of FDA regulation of sunlamps since 1974, identifies and critiques the overriding rationale of consumer choice as the background for relatively lax FDA regulations, and discusses the possible ways in which FDA regulation of sunlamps can change to better suit the FDA's role in protecting consumers from dangerous products. Proposals for sunlamp regulation are identified and analyzed, leading to the conclusion that more effective regulation of sunlamp use requires at least some abandonment of the consumer choice rationale in sunlamp regulation.

Introduction

"The United States Department of Health and Human Services and the World Health Organization's International Agency for Research on Cancer have classified UV radiation from tanning devices as carcinogenic to humans, in the same category as tobacco and tobacco smoking. A review of seven studies found a 75 percent increase in melanoma in those who had been exposed to UV radiation from indoor tanning before the age of 35."¹

"You might be surprised at the number of benefits of tanning beds. Obviously, the most obvious benefit is developing a wonderful tan. Typically, as summer approaches, people will begin to visit the local tanning salon to establish a base tan so when they do go outdoors in the sun they do not burn, or to develop a rich tan that looks as if they just came

¹ American Academy of Dermatology and AAD Association. Position Statement on Indoor Tanning, November 14, 2009. Available: www.aad.org/.../Position%20statements/PS-indoor-tanning.pdf.

back from vacation in Hawaii. Then, there are other individuals who have a special function to attend whereby they want a healthy glow.”²

“While indoor tanning is a cosmetic service, a well-known side effect of exposing the skin to ultraviolet (UV) light is the production of vitamin D. Emerging evidence suggests that there may be an epidemic of vitamin D deficiency in North America. Research also suggests that vitamin D plays an important role in maintaining good health.”³

“[A] common misperception is that indoor tanning protects you from sun damage by providing a base tan, and can be a safe source of vitamin D. Both are false.”⁴

“[T]he agency believes that sunlamps perform a function desired by the consumer and, consequently, has not penalized the prudent individual by removing this potentially hazardous product from the marketplace.”⁵

“If you’re confused about the health effects of indoor tanning, rest assured: You’re not alone. For decades, the American Academy of Dermatology, the Skin Cancer Foundation, and other medical groups have pounded home the message that it’s a dangerous practice and should be avoided. Many dermatologists suggest that the tanning industry, like the

² Tanning Info Center. The Benefits of Tanning Beds. Available: <http://www.tanninginfocenter.com/benefits-of-tanning-beds.html>.

³ The Indoor Tanning Association. “Positive Effects of UV Light.” Available: http://www.theita.com/?page=Positive_Effects_UV.

⁴ McCook, Alison. “Many ignore indoor tanning risks.” Reuters, 2010. Available: <http://www.reuters.com/article/2010/12/21/us-indoor-tanning-idUSTRE6BK44L20101221>.

⁵ 21 CFR §1002 (1985).

tobacco industry before it, is manipulating and distorting scientific evidence to protect a dangerous product.”⁶

There is little question that UV exposure is carcinogenic. Sunlamps emit ultraviolet radiation in selected wavelengths. Though also used therapeutically, sunlamps are associated with indoor tanning and the cosmetic effect of darker skin that UV exposure causes. Since the advent of sunlamps and their growing popularity in the United States, the risks posed by UV radiation can be accessed via indoor tanning facilities. This paper explores FDA regulation of sunlamps used for cosmetic purposes, and questions the validity of consumer choice as a rationale for allowing their continued existence on the market. Part I presents a history of FDA regulation of sunlamps from 1974 to the present day, and concludes that little about their regulation has changed since sunlamps entered the market. FDA regulation has continued to focus on labeling requirements with the goal of informing consumers about the dangers of sunlamps to enable them to make informed choices about their use. Part II discusses the scientific evidence pertaining to the dangers of sunlamp use. Sunlamps emit UV radiation, which damages skin and causes DNA mutation of subcutaneous cells. These mutations in turn lead to the development of cancerous cells. Part III introduces state regulations pertaining to sunlamp use, showing that states’ emphasis is on the appropriate age to begin tanning. States’ responses to the dangers of tanning show that there is still an important role for the FDA to play in protecting consumers from dangerous products. Though age-based restrictions are an important step

⁶ Voiland, Adam. “The Indoor Tanning Industry Wants You.” US News Health, 2008. Available: <http://health.usnews.com/health-news/family-health/articles/2008/06/25/the-indoor-tanning-industry-wants-you>.

in ensuring that consumers of sunlamps have the maturity necessary to balance the risks and benefits of indoor tanning, consumer confusion still abounds and FDA action is sorely needed. Part IV discusses the tax on indoor tanning levied by §10907 of the Patient Protection and Affordable Care Act (PPACA). The tax's effect remains to be seen, but it appears a step in the direction of incentivizing consumers to reconsider the desirability of indoor tanning. PPACA's mention of indoor tanning indicates an acknowledgment by our federal government of the dangers posed by indoor tanning, and suggests that avenues outside of the FDA are also available for protecting consumers from the dangers of sunlamp use. Part V discusses potential avenues for future FDA regulation of sunlamps, concluding that reclassification of sunlamps as Class II Medical Devices would constitute an important move by the FDA in reducing consumer use of sunlamps. Part VI weighs concerns about governmental paternalism with the value of consumer choice, concluding that the FDA's role in balancing these values requires more weight in favor of protection of consumers. Part VII surveys several recent court cases pertaining to injuries from sunlamp use, and considers lessons these cases may provide for advocates of consumer choice. Ultimately, the dangers of sunlamps are serious, and this paper concludes that more stringent regulation of the indoor tanning industry by the FDA is necessary.

I. History of Sunlamp Regulation by the FDA

Despite continuing recognition of the dangers of indoor tanning, the FDA has chosen to allow the use of sunlamps for cosmetic purposes, citing the importance of consumer choice. Since the FDA began its regulation of sunlamps, it has focused upon ensuring that these devices are accompanied by information that should permit the reasonable consumer

to make a decision regarding the risks and benefits of sunlamp use. Sunlamps first made their appearance in Europe in the 1970s as winter-weary individuals sought an alternative to natural sunlight⁷. In the 1970s, indoor tanning made its way to the United States and gained popularity.⁸

The FDA first began to tackle regulation of “sunlamps” in 1974, at which time it was already known that indoor tanning carried risks to skin health. In 1974, sunlamp makers were required to report injuries caused by the use of sunlamps⁹, but the FDA requested more information about the risks that they posed to the consumer.¹⁰ Acknowledging the “potential hazard” posed by sunlamps, the FDA opened the topic of sunlamp regulation to notice and comment. While the carcinogenic nature of tanning was as yet unknown in 1974, serious injuries from the use of sunlamps had already been reported, such as severe burns and retinal damage. In 1975, the FDA invited comments on a wider range of questions related to sunlamps. Considering rulemaking on sunlamps, the FDA inquired as to what class of products sunlamps should fall into, the sort of performance standard that should be instituted for sunlamps, whether sunlamps should be usable in household sockets, the health risks posed, the constitution of future warning labels, and the environmental effects of sunlamps. Also in 1975, the FDA distinguished sunlamps used in the healthcare setting, defining its regulation as applying only to those sunlamps used without the aid of a physician or physical therapist.¹¹

⁷ Drummond, Katie. “Indoor Tanning Gets a Moment in the Sun. March 29, 2010. Available: <http://www.aolnews.com/2010/03/29/indoor-tanning-getting-unwanted-moment-in-the-sun/>

⁸ *Id.*

⁹ 21 C.F.R. § 1002 (1974).

¹⁰ *Id.*

¹¹ 21 C.F.R. §1020 (1975).

The first comprehensive regulation of sunlamps by the FDA was proposed in 1977 and was “intended to reduce the possibility of sunlamp-related injury by reducing unnecessary exposure and overexposure to sunlamp radiation.”¹² In the years intervening since the FDA first recognized the need to regulate sunlamp exposure, the National Electronic Injury Surveillance System, run by the Consumer Product Safety Commission, had estimated that sunlamps caused thousands of injuries per year resulting in visits to the emergency room.¹³ The first tests on laboratory animals exposed to sunlamps had also yielded results suggesting that sunlamps may cause skin cancer.¹⁴ Though tests on laboratory animals are not conclusive evidence of a device’s effects on humans, in the case of sunlamps ethical considerations dictate the impossibility of conducting human trials. Nevertheless, given the scientific community’s understanding of UV radiation’s effect on skin and the results of such animal studies, it is safe to conclude that the current state of scientific understanding leaves little doubt that UV radiation from sunlamps poses serious danger to the skin of consumers.

In responding to the concerns raised by such reports, the FDA Commissioner could have taken one of a number of courses of action. As described in the 1977 proposed rule, the Commissioner could have used the defect provisions of the Public Health Service Act, set forth voluntary recommendations for sunlamp makers, or created a product performance standard. Examining these options, the Commissioner found that using defect provisions would be problematic because they are not prospective, and voluntary

¹² 21 C.F.R. §1040 (1977).

¹³ *Id.*

¹⁴ *Id.*

recommendations lack the enforcement ability of performance standards.¹⁵ The defect provisions of the Public Health Service Act would essentially have allowed the Commissioner to claim that sunlamps possess a defect that makes them ineligible for sale in the United States. Conceivably that defect could be carcinogenicity or general impact on skin health. Voluntary recommendations would permit the FDA to give the tanning industry flexibility in meeting the suggestions by the FDA, but since enforceability is important when protecting the safety of consumer products the advantage of voluntary recommendations over product performance standards is slim. Settling on the use of “mandatory product performance standards,” the Commissioner acknowledged that this route would not mitigate all risks from sunlamps, and that the FDA was open to the possibility of stronger consumer protection, more comprehensive use restrictions, and even banning the use of sunlamps outside the prescription setting.¹⁶

The first final rule regarding sunlamps was promulgated in 1979. In addition to setting forth a performance standard for the use of sunlamps in the United States, in the Federal Register the FDA considered and responded to comments made regarding the proposed rule. Ultimately, though the FDA acknowledged the risks posed by sunlamp use, it concluded that “sunlamps perform a function desired by the consumer, and consequently, has not penalized the prudent individual by removing this potentially hazardous product from the marketplace.”¹⁷ Essentially, the FDA’s regulation of sunlamps appears to have started from the premise of guarding consumer choice. The 1979 regulations defined sunlamps as a medical device, because the FDA believed the therapeutic function of

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ 21 C.F.R. §1002 (1979).

sunlamps for use in treating disorders like psoriasis could not be readily separated from the cosmetic use of the product.¹⁸ In order to protect consumers in both therapeutic and cosmetic contexts, the FDA decided to promulgate performance standards for sunlamps generally as a medical device. The question of distinguishing between therapeutic and non-therapeutic uses of sunlamps presented an issue of contention, and the FDA also indicated in 1979 that its regulations were meant to apply only to sunlamps meant for cosmetic use, presumably under the assumption that therapeutic uses of sunlamps would include physician supervision and therefore that consumers in that setting do not need the same protections. However, in 1979 the FDA also acknowledged, “there may be no safe threshold level for exposure to ultraviolet radiation.”¹⁹ The FDA initially got involved to ensure the safety of sunlamps used in the United States, but from the inception of the FDA’s regulation of sunlamps the emphasis has been on consumer choice. While recognizing the known dangers of sunlamp use, the FDA’s focus was almost exclusively on labeling requirements designed to inform the consumer. Some regulations of the actual use of sunlamps were also promulgated in 1979, such as a ten-minute maximum for exposure, and requirements for the use of protective eyewear. The bulk of the 1979 rules were dedicated, however, to ensuring that adequate labeling informed the consumer of the dangers of sunlamp use. The tanning industry balked at the labeling regulations, arguing in a comment that the FDA does not require labels as comprehensive on cigarettes, which are known to be dangerous to human health. Sidestepping the comparison, the FDA simply indicated that cigarettes were not the subject of the particular regulation at issue.

¹⁸ *Id.*

¹⁹ *Id.*

Since the 1979 regulations, sunlamp performance standards have changed minimally to accommodate changes in sunlamp technology and the development of new sunlamp products. The wavelength range of light for which the sunlamp regulations apply has been changed, from 180-320 nm to 200-400 nm, in keeping with the changing wavelength coverage of new sunlamps.²⁰ The FDA also changed the applicability of its regulations to sunlamps that emit UVA (as opposed to UVA and UVB) radiation.²¹ Additionally, the FDA altered the warning labels, requiring a statement that individuals that do not tan easily in natural sunlight are unlikely to achieve the desired cosmetic tanning effect from the use of sunlamps.²²

The current FDA stance on sunlamps intended for cosmetic purposes defines sunlamps as a Class I Medical Device, the least regulated category for medical devices. In March 2010, the FDA convened its Advisory Committee to consider changes to its rules regarding sunlamps. While the option of reclassifying sunlamps as Class II medical devices, thus strengthening the restrictions on their marketing and use, was on the table, the FDA concluded in May 2010 that they would remain Class I devices but that warning labels should be strengthened. The FDA filed a report with Congress in response to a mandate from 2007, elucidating the need for clearer warning labels and better positioning for the labels. The FDA consulted focus groups to determine the most effective way to communicate risks of indoor tanning to consumers. Through a number of rulemakings, however, the FDA's classifications and requirements for sunlamps have essentially

²⁰ 21 C.F.R. §1040 (1985).

²¹ *Id.*

²² *Id.*

remained unchanged: with adequate labeling and a few other restrictions, the FDA allows consumers to use sunlamps at will.

II. Dangers of Sunlamp Use

The risks posed by UV light are well-documented, and links have been made between sunlamp use and the likelihood of developing melanoma and other skin diseases.²³ Since 1974, more and more information has been gathered indicating the risks associated with use of sunlamps, and several advocacy organizations have requested that the FDA change its permissive stance toward sunlamps. In 1992, the International Agency for Research on Cancer released its review of evidence regarding the dangers of sunlamp use. It concluded that radiation from sunlamps is strongly linked to skin cancer, particularly melanoma.²⁴ A recent study in *Pediatrics* provides an overview of the scientifically known risks of sunlamp use to date, and the results are grim. Not only do animal studies show that UV light possesses carcinogenic properties²⁵, but UV light is also known to cause sunburn, skin damage, skin aging, and photosensitivity.²⁶ Exposure to UV light has been linked to many serious skin problems, from photoaging to age spots to

²³ American Academy of Dermatology. "Indoor Tanning." Available: www.aad.org/media-resources/stats-and-facts/prevention-and-care/indoor-tanning.

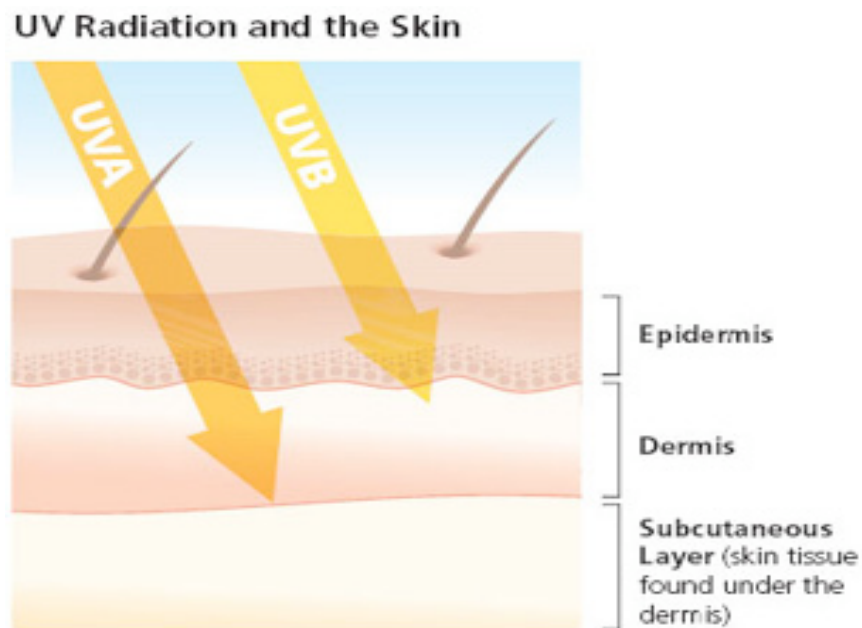
²⁴ International Agency for Research on Cancer. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 55: Solar and Ultraviolet Radiation. Summary of Datae Reported and Evaluation*. Geneva, Switzerland: World Health Organization; 1997. Available at: <http://monographs.iarc.fr/ENG/Monographs/vol55/volume55.pdf>. Accessed April 20, 2011.

²⁵ Balk, Sophie and the Council on Environmental Health and Section on Dermatology. "Technical Report Ultraviolet Radiation: A Hazard to Children and Adolescents." *Pediatrics*, Feb. 28, 2011, pg. e794.

²⁶ *Id* at 793-794

multiple forms of skin cancer.²⁷ UV radiation has specifically been shown to cause cancer through its effects on skin's cellular DNA. Absorption of UVA and UVB light by the skin's layers leads to genetic mutations that are known to cause cancer.²⁸ UVB light absorbs into fewer layers of human skin, and is thus less likely to be carcinogenic than UVA light. Unfortunately, sunlamps are manufactured to primarily emit the more dangerous UVA radiation.²⁹

Figure 1: Absorption of UVA and UVB light by the skin.³⁰



The cosmetic effect of tanning actually signals that the skin has experienced damage as a result of UV radiation. Skin becomes darker in response to UV exposure in an attempt to protect its DNA from further injury. Essentially, DNA in the skin mutates in order to protect

²⁷ "UV Skin Damage in a Different Light. NIH, 1998. Available: www.nih.gov/news/pr/aug98/nigms-31.htm.

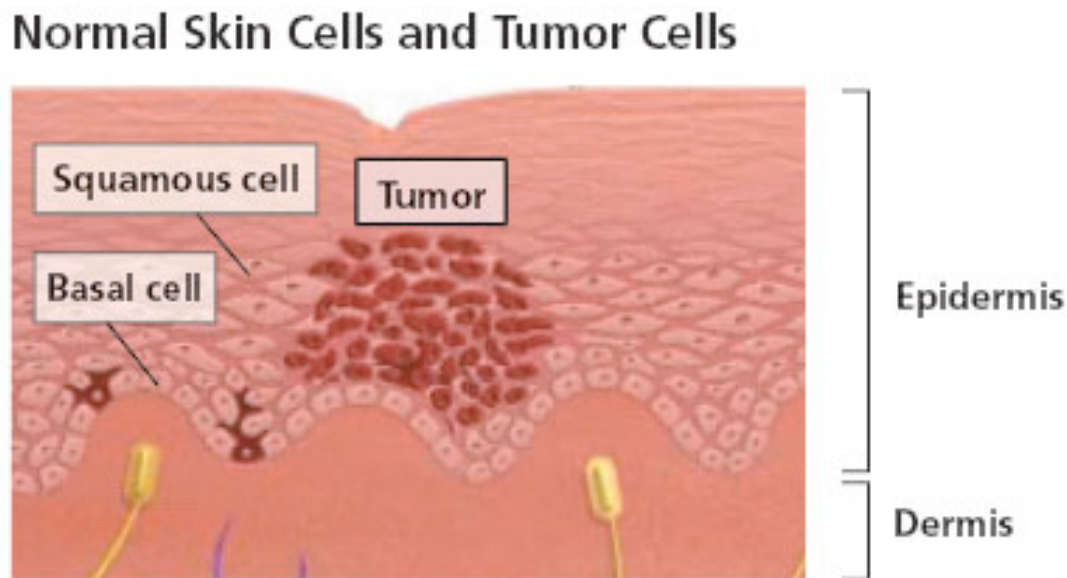
²⁸ "UV Information." www.skincancer.org/understanding-uva-and-uvb.html.

²⁹ *Id.*

³⁰ *Id.*

itself, and these mutations are known to cause various forms of skin cancer.³¹ Tumors eventually grow on the skin as a result and commonly known symptoms such as moles or discolorations occur on the skin.

Figure 2: Growth of tumor cells on the skin.³²



The effects of UV light on skin can be mitigated through the use of sunscreen products and by avoiding direct exposure to the sun; however, the use of sunlamps increases individuals' normal exposure to UV radiation and thus the risk of developing skin cancer. The cosmetic effects promised by the tanning industry, darker skin as a result of using sunlamps, appears to be directly related to the development of cancerous skin cells.

Given the wealth of scientific evidence regarding the dangers of sunlamp use, it seems antithetical to the FDA's role in our government that regulation of sunlamps is so lax. UV light, upon contact with skin, essentially sets off a carcinogenic process that leads to

³¹ *Id.*

³² *Id.*

dangerous skin disorders. Given such a strong causal link between exposure to UV light and cancer, it is surprising that the FDA has not taken a more active role in mitigating or removing this danger from the market. Sunlamps have been likened to cigarettes in their carcinogenic quality, but one key distinction may serve to explain the FDA's reticence in restricting access to sunlamps: unlike cigarette use, even those who do not use indoor tanning facilities are exposed to damaging UV light. Sunlamps, as per their name, are meant in many respects to mimic the effects of the sun. Though rates of skin cancer have increased dramatically since sunlamps entered the market, exposure to the carcinogenic UV light they emit occurs naturally as well. Nevertheless, given the controlled nature and increased intensity of UV light emitted by sunlamps, data on the effects of UV exposure on skin is very relevant to determining the safety of sunlamps and indoor tanning. Those who are exposed to UV light through nature can take steps to protect themselves: sun block, hats, and shade are common options. However, those who consume indoor tanning services are seeking out exposure to the harmful rays that science has shown are likely to cause cancer.

III. State Regulation of Sunlamps

Many states have taken steps in addition to those taken by the FDA to ensure consumer safety in the realm of sunlamp use. These regulations restrict or ban use of sunlamps by minors, though no state has enacted an outright ban on sunlamp use, nor have restrictions based on skin sensitivity, etc. been introduced. One interesting step taken by several states has been to ban indoor tanning by minors without a physician's prescription. Taking the decision out of minors' hands is not a particularly new idea- we do this with

other substances such as alcohol and tobacco; however, requiring a physician's approval for indoor tanning essentially removes the option of tanning for cosmetic purposes by minors. This additional step toward protecting minors from unnecessary UV exposure could potentially form a basis for future regulation by the FDA for all consumers. Requiring a physician's prescription constitutes a paternalistic policy in this area, and would be out of keeping with the FDA's current permissive stance on sunlamp use, but could be a policy considered if the FDA reconsiders its regulation of sunlamps.

Figure 3: Current and Pending State Regulations of Sunlamp Use by Minors³³

Arkansas	Parental signature required under 18.
Arizona	Written parental permission required under 18.
California	No tanning for children under 14, and under 18 a parental signature is required. Pending state legislation would ban tanning for all minors.
Connecticut	Written permission from a parent required under the age of 18. Pending legislation would require that parent accompany the child for each tanning session.
Delaware	No tanning for children under 14, and parental signature as well as presence required for those under 18.
Florida	Not tanning for children under 14, and written parental permission required under 18.
Georgia	No tanning for children under the age of 14, and written parental permission required for those under 18.
Illinois	No tanning for children under the age of 14, parental consent required under the age of 17. Pending legislation would extend the tanning ban to anyone under 18.
Iowa	Pending legislation would require physician's prescription for those under 18.
Indiana	Children under 16 must be accompanied at facility by a parent. Parental signature of waiver at tanning facility required under the age of 18.
Kentucky	Children under 16 must be accompanied by a parent, and parental waiver must be signed for those under 18 (waiver is valid for one year after signature). Pending legislation would prohibit those under 14 from tanning.
Louisiana	Children under 14 must be accompanied by a parent, and written parental consent is required for those under 18.
Maine	No tanning for children under 14, and those from 14-15 must be accompanied by a parent. Parental consent required for those under 18 (consent valid for one year). Statute explicitly requires presenting parents with materials that warn about the risks of indoor tanning.
Maryland	Parental consent, given at tanning facility, required for those under 18. Pending legislation would ban minors from using indoor tanning facilities.
Massachusetts	Parental consent required between the ages of 14 to 17. No tanning for those under 14. Pending legislation would ban indoor tanning for those who are under the age of 16.
Michigan	Parental consent and acknowledgement of dangers of tanning required for those under 18.
Minnesota	Parental signature on warning statement required for those under 16. Pending legislation

³³ "Tanning Restrictions for Minors- A State-by-State Comparison." Aim at Melanoma. Available: <http://www.aimatmelanoma.org/aim-for-a-cure/legislative-accomplishments-in-melanoma/tanning-restrictions-for-minors.html>.

	would ban tanning under the age of 18 without physician's prescription.
Mississippi	Written parental consent required for those under 18. Consent valid for a year, but must indicate the number of sessions it is valid for.
Missouri	Several pending pieces of legislation would prohibit tanning under the age of 16 and require parental presence at the tanning facility for those under the age of 18.
Nevada	Pending legislation would require written parental consent for those under 18.
New Hampshire	Physician approval required under the age of 14, and parental consent and accompaniment required under the age of 18.
New Jersey	No tanning for children under the age of 14. Parental consent required for those under 18. Pending legislation prohibits tanning for those under 18 altogether.
New Mexico	Pending legislation bans those under 18 from indoor tanning.
New York	No tanning for children under 14. Parental consent, given in writing and in presence of tanning facility operator, required for those under 18. Consent valid for one year from date of signature. Several pieces of pending legislation would either prohibit tanning for those under 16 or those under 18.
North Carolina	No tanning under the age of 13 without physician's prescription. Pending legislation would raise the age for indoor tanning to 18.
North Dakota	No tanning without physician's prescription for those under 14. Signed parental consent required for those under 18, valid for one year.
Ohio	Parental consent before every tanning session required for those under 18. Pending legislation requires physician's prescription for use of a tanning bed by those under 18.
Oregon	Parental consent required under the age of 18, signed in the presence of tanning facility operator.
Pennsylvania	Two pieces of pending legislation. One would require a physician's prescription for those under 18, and the other would prohibit tanning for those under 14 without a doctor's prescription and would require parental accompaniment for those under 18.
Rhode Island	Parental consent form required for those under 18. Pending legislation would require physician's prescription for those under 18.
South Carolina	Written parental permission required, given in the presence of a tanning facility operator.
South Dakota	Pending legislation would require parental consent under the age of 18.
Tennessee	Parental consent required for those under 18. Must be notarized.
Texas	Parental consent required for those under 18.
Utah	Parental consent and presence at first tanning session and once every 12 months thereafter required for those under 18.
Vermont	Pending legislation would ban use of indoor tanning under the age of 18.
Virginia	Written parental consent required under the age of 15. Parents must also indicate their child's skin type. Valid for 6 months.
Washington	Two pieces of pending legislation would require a physician's prescription for those either under the age of 16 or the age of 18.
West Virginia	Pending legislation would require parental accompaniment for those under 14 and written parental consent for those under 18.
Wisconsin	No tanning for those under the age of 16.
Wyoming	Parental consent, signed in presence of tanning facility operator, required for those under 18. Consent valid for one year. Children under 15 must be accompanied by a parent during every visit.

IV. PPACA Tanning Tax

The Patient Protection and Affordable Care Act (PPACA), Section 10907, imposes a 10% excise tax on the use of tanning beds³⁴. The tax must be paid by consumers of indoor tanning services, and is expected to reduce profits for the tanning industry. The joint goals of the tax are to encourage people to make safer decisions about tanning and to help pay for other measures in the Act. Since the tax became law in July 2010, indoor tanning facilities must charge an additional 10% of their regular rates to clients. From an economic perspective, it seems that an incentive is being put in place to move consumers in the direction of less tanning. The effect of this tanning tax on consumption of indoor tanning services remains to be seen. Ten percent may not be high enough to deter those who wish to secure the cosmetic effects provided by indoor tanning, but it seems a step in the direction of more aggressive consumer protection. Consumers are still allowed choice in the tax scenario, but the tanning tax makes a move away from the FDA's emphasis on consumer choice. Though not coercive in the sense that the tax does not ban access to tanning services, it is at least slightly paternalistic given that PPACA's drafters have identified a consumer activity they believe is unhealthy and have aimed taxation at that activity in the hopes of incentivizing safer choices.

V. FDA Options for Regulation of Sunlamps

Regulation by states and the federal government through legislation outside the scope of the FDA may serve to enhance consumer safety in sunlamp use, but the FDA still has a continuing obligation to ensure the safety of consumer products that fall within its

³⁴ U.S. Department of the Treasury, Internal Revenue Service, "Indoor Tanning Services; Cosmetic Services; Excise Taxes," 75 *Federal Register* 33740, June 15, 2010.

purview. These other options for regulating and discouraging sunlamp use by consumers may or may not be effective, but the question remains as to the proper role that the FDA should play in their regulation. Recent reports on FDA's activity in the area of sunlamp regulation show willingness to consider more intrusive regulations, but recent regulations have fallen on the side of favoring consumer choice over consumer protection. The majority of FDA regulation throughout the history of sunlamp use in the United States has focused on the promulgation of labeling requirements that disclose the dangers of tanning, and suggested duration and frequency of exposure. In seeking to protect consumer autonomy, it seems that the FDA has forsaken the possibility of more aggressive measures. Given the popularity of indoor tanning, it seems likely that warnings alone will not deter those who wish to secure the cosmetic effects of sunlamp use.

When deciding how to classify sunlamps, the FDA Commissioner faces a number of options. Banning sunlamps outright has always been an option, but one the FDA has shied away from on consumer choice grounds. Given their dangerous nature, the FDA could also have classified sunlamps as Class II or Class III medical devices. The standard for classifying a device as Class II or III is based on the dangerousness of the device at issue and the extent of scientific knowledge as to the danger that the device poses to the consumer. Since sunlamps cannot directly be tested on humans due to research ethics concerns, the knowledge regarding their effects is either anecdotal or based on animal studies. Animal studies have shown links between exposure to UV radiation and skin cancer, and though the FDA has recognized causal links between sunlamp use and melanoma, it has persisted in taking a relatively hands-off approach to regulation in this area.

If the FDA were to entertain stricter regulations on sunlamps, a number of important revisions in current law seem in keeping with the need to protect American consumers. First, federal age limits on sunlamp use would respect the consumer choice rationale the FDA has espoused in this area while ensuring that young users do not endanger their health. As a society, we have accepted that individuals under the age of eighteen have not matured enough to make decisions such as who to vote for, whether to smoke cigarettes, and whether to drink. By extension, it seems we have determined that the balancing of risks and benefits expected of adults cannot also be expected of minors; therefore, the consumer choice rationale does not apply to them. At the least, requiring parental consent for use of sunlamps would ensure that the risks have been adequately taken into account by an individual responsible for the minor. Second, reclassification of sunlamps as Class II or Class III medical devices would put the tanning industry on notice that more than labeling and nonintrusive usage requirements would emerge from future FDA regulation. While individuals who use tanning booths are required to cover their eyes and there are time limits on sunlamp use, they are otherwise left to their own devices regarding sunlamp use. It is, of course, questionable as to whether a balance between more regulation and consumer choice can be struck. If sunlamp use is carcinogenic, after all, it is possible that the FDA should outlaw their use altogether. It would not be feasible to maintain records of consumers' sunlamp use to ensure that they do not exceed a certain number of uses in a week, but perhaps individual tanning establishments could be required to establish limits on the use of their patrons. Third, requiring a physician's prescription may provide an avenue for regulation of sunlamps that does not completely outlaw their use. While an accepted method used by states for restricting minors' use of sunlamps, a

prescription requirement would likely destroy the indoor tanning industry. Given the dangers of UV light, it is unlikely that physicians would be eager to help their patients gain access to such services. If prescription requirements would effectively constitute an outright ban, the FDA may not be willing to go that far.

VI. Paternalism and Consumer Choice

The line between paternalism and the protection of consumers is rarely clear, but in the case of sunlamps it does not seem that the FDA has even come close to toeing that line. In its 1985 regulation setting a performance standard for sunlamps, the FDA identified the need to “protect the consumer from sunburns... and from exposure to hazardous radiation that is unnecessary for skin tanning,” but concluded, “FDA believes that the user of a sunlamp can take appropriate action when informed of the possible adverse effects to the body from exposure to ultraviolet radiation, if the product is equipped with necessary safety performance features.” Despite acknowledging the dangers posed to users of sunlamps for cosmetic purposes, the FDA’s 1985 regulation dealt minimally with safety features of sunlamp use (focusing on eye protection and time limits for tanning), and focused on the labeling requirements for sunlamp products.³⁵ The FDA’s original role in government focused on identifying adulterated or inaccurately labeled products. In that role, analysis of risks and benefits plays only a minor part; however, with the expansion of the FDA’s purview to a variety of drugs and devices the “agency increasingly is required to determine the level of risk acceptable in products that are properly manufactured and used

³⁵ Sunlamp Products; Performance Standard. 50 Fed. Reg. 36548 (September 6, 1985).

as intended.”³⁶ The expanded role of the FDA since 1938 requires the agency’s priorities to shift, and cost-benefit analyses of products entering the market are likely to increase in importance. In the case of sunlamps, there is little question that their use poses dangers to the consumer. Cosmetic benefit in the form of darker skin seems to pale in comparison to melanoma, premature aging, and skin discoloration. While the tanning industry insists that its products are safe for consumption, the FDA’s role should be to look at such claims skeptically and consider whether the average consumer can make appropriate choices regarding the health of their skin. Given the continuing popularity of indoor tanning as well as the epidemic proportions of skin cancer diagnoses, it seems that a new balance should be struck.

How strong is the apparent reasoning for the FDA’s decision to leave sunlamps accessible to consumers? If no safe level of sunlamp exposure exists, then would a reasonable and informed consumer *ever* choose to use sunlamps? Consumer choice is an important value, as we would all like to feel that we have control over what products we use, as well as over the risks we decide to take. If indoor tanning can be construed as an informed choice by the consumer to accept risks in favor of cosmetic benefits, as the FDA has treated it, then it does not seem particularly problematic to keep sunlamps minimally regulated. If, however, it could be argued that consumers do not have all the facts about sunlamps’ dangers, then more stringent FDA regulations would be in order. The carcinogenic effects of UV exposure are now well known, so it is conceivable that the FDA’s position on sunlamp regulation reflects a belief that consumers have weighed the pros and cons of indoor tanning and those that choose to use sunlamps do so with their eyes open

³⁶ Richard A. Merrill, *Risk-Benefit Decisionmaking by the Food and Drug Administration*. 45 George Washington Law Review 994 (1977).

(figuratively speaking). Nevertheless, it could also be argued that if the carcinogenic effects of exposure to UV radiation are truly so well-known, then it is antithetical to the FDA's role as a gatekeeper for deciding which substances are too dangerous for human consumption to allow sunlamps to continue to permeate the market with so little regulation. Just as the FDA may set limits on mercury levels in fish or antibiotic levels in meat, it seems in keeping with its role to expect that the FDA would impose stricter regulations on sunlamps.

VII. Caselaw on Consumer Use of Sunlamps

Several recent court cases indicate that the consumer choice rationale may be flawed. Two predominant types of cases have appeared in recent years: cases where the plaintiff argues that advertising of indoor tanning is misleading, and cases in which a plaintiff suffered harm from sunlamp use. Though the claims and legal arguments differ, the results indicate the same conclusion: consumers are not fully informed of the dangers sunlamps pose to their health, and the tanning industry's efforts at consumer safety and information leave something to be desired.

Several cases in the past several years have explored the possibility that the tanning industry distorts the risks and benefits of tanning, leaving consumers with an inadequate understanding of the effects of indoor tanning. In Nafar v. Hollywood Tanning, 339 Fed.Appx. 216, 2009 WL 2386666 (C.A. (N.J.)), the plaintiff consumer claimed that defendant Hollywood Tanning failed to adequately represent the dangers of indoor tanning to her and others like her. Though Hollywood Tanning complied with FDA labeling regulations, Nafar claimed that the company's employees informed her that the dangers of indoor tanning were minimal. Parts of the case were eventually dismissed due to choice of

law and class certification issues, but the claims made by Nafar deserve closer analysis. The defendant here allegedly distorted the benefits of indoor tanning, promising a better complexion and possible treatment of skin disorders such as acne and psoriasis. Outside of the FDA-required warnings, Nafar claims the defendant did not provide any information about the carcinogenic nature of sunlamp use, and that she would not have used Hollywood Tanning's services if she had been apprised of these dangers. Though the FDA expects its regulations to lead to safer decisions by consumers, it seems that in Nafar's case the required labels did not lead in the direction of an informed choice. Protection of consumer choice is premised on the conception of the consumer as reasonable person faced with all relevant information in making a decision; here, Nafar claims that she was deprived of the ability to make such a choice.

In In re Toshiba America HD DVD Marketing and Sales Practice Litigation, 2009 WL 2940081, the court admitted, "the average consumer's knowledge of the harmful effects of indoor tanning is a disputed issue." While the FDA's required warnings are meant to apprise the consumer of the risks of indoor tanning, it seems that there is something of a chasm between consumer knowledge and the knowledge of the FDA. If consumers are not equipped with the appropriate information to make an informed choice, should the FDA change labeling requirements, or does the solution lie in more restrictive usage requirements?

The balance between paternalism and freedom may be difficult to strike, but if court cases regarding particularly egregious injuries to consumers are any indication, it may be time for the FDA to move in the direction of paternalism when it comes to sunlamps. In Swindle v. Body Blasters Gym, Inc., La.App. 2 Cir. 1999, the plaintiff's skin turned purple

after using defendant's indoor tanning facilities. The plaintiff had been taking medication that made her skin more sensitive to UV light, and she blamed the extreme results she experienced on the defendant's company's negligent failure to warn her of the possibility that certain medications intensify the effects of indoor tanning. The court found that the FDA-required warning labels had been present at the gym during her use of the facilities, and dismissed her case. Of note in the Swindle case is the court's equation of reasonable care with meeting the FDA's requirements. Vendors of sunlamp services are not responsible for providing any more warning than that required by the FDA, and thus the FDA's regulations take on a great deal of importance for consumer safety. The FDA's role in essentially defining the negligence standard for sunlamp operators means that its required labels are the only protection consumers can expect.

In Faranso v. Cass Lake Beach Club, Inc., Mich.App. 1998 WL 1991226, the plaintiff sustained severe sunburns when she fell asleep in a tanning bed and awoke over an hour later. She sued defendant Cass Lake Beach Club for negligence in operating their facilities, but lost the case because she signed a waiver of liability that the court found valid. Ms. Faranso read and signed a sheet of paper indicating that she would not hold the defendant liable for any damages from using their tanning beds. The court found that since Ms. Faranso was not incapacitated in any way when she signed the waiver, it was valid and Cass Lake Beach Club was not liable for her injuries. The Faranso case shows that courts expect consumers to inform themselves of the dangers of sunlamp use and in addition to making the decision whether to use sunlamps courts expect that consumers can reasonably decide whether to sign a liability waiver. Liability waivers are common in many industries, and given that sunlamps pose health dangers to their users, it makes sense that operators

of indoor tanning facilities would pursue this avenue to protect themselves from liability. In fact, the relative dearth of cases regarding indoor tanning injuries despite the statistics on actual injuries sustained in the United States as a result of their use may be related to the use of such waivers by operators of tanning facilities.

Claims of misinformation, negligence, and mistake appear in the above cases, and they demonstrate some serious problems with the consumer choice justification offered by the FDA in its regulation of sunlamps. It could be argued that despite adequate warnings, some consumers will make the choice to use sunlamps for cosmetic purposes. Be that as it may, the question then arises whether the FDA's role should be limited to sharing information about the dangers and providing for minimal safety standards, or whether it is time for more aggressive measures.

Conclusion

FDA regulation of sunlamps since 1974 has left the cost-benefit analysis regarding their use to the consumer. Aside from a few nonintrusive usage requirements, the FDA has focused almost exclusively on informing the consumer about the dangers of indoor tanning and leaving the decision to consumer discretion. Given the increasing popularity of sunlamp use, the skyrocketing rates of skin cancer in the United States, and expressions of consumer dismay when they are in fact injured by sunlamp use, it is safe to say that the FDA's efforts to inform consumers have not been successful to date. State efforts to protect minors appear to work, but these efforts have been based on a paternalistic rationale it would be difficult to extend to adult consumers. PPACA's tanning tax may be an intermediate solution to the difficulty of regulating sunlamp use while ensuring consumer

choice. By nudging consumers in the proper direction, the tax may reduce some consumers' usage of sunlamps while ultimately leaving the cost-benefit analysis in the hands of consumers. As a relatively new tax, the effects of PPACA's tanning tax are not yet known, but it does seem to be a step in the right direction.

Despite the existence of several options for regulating sunlamp use, injuries from sunlamp use and the dangers of UV exposure dictate that the FDA should reconsider its support of consumer choice and get more involved in protecting consumers from the dangers of sunlamp use. At the very least, reclassification of sunlamps as a Class II Medical Device, subjecting them to more rigorous examination and regulation by the FDA, appears to be called for. Reclassification would continue to provide consumers with the choice of whether to engage in indoor tanning while hopefully serving to explore whether there is any way to reduce the risks that consumers face. Such action by the FDA would respect the autonomy of consumers while enabling regulators to get more involved in demanding more from the tanning industry.